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NATERA, INC.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA,
SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,

Plaintiff,

vs.

NATERA, INC.,

Defendant.

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CASE NO. 3:21-CV-04062-EMC

**NATERA, INC.'S EMERGENCY MOTION
FOR ORDER AUTHORIZING NRG
DEPOSITION**

REDACTED FOR PUBLIC FILING

Date: October 15, 2024
Time: 9:00 am
Place: Courtroom 5, 17th Floor
Judge: Hon. Edward M. Chen

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on October 15, 2024 at 9:00 am or as soon thereafter as the matter may be heard in the court room of the Honorable Edward M. Chen, Courtroom 5 on the 17th floor of the San Francisco Courthouse located at 450 Golden Gate Avenue, San Francisco, CA 94102, Defendant and Counterclaim Plaintiff Natera Inc. (“Natera”) will and hereby does move for an order authorizing a deposition of third party NRG Oncology (“NRG”) based upon Natera’s timely-served subpoena of May 16, 2024. Despite producing documents up and until August 15, 2024, NRG has refused to sit for a deposition based upon Guardant’s objection.

This Motion is based on the Notice of Motion and Motion, the Memorandum of Points and Authorities, the Declaration of Elle X. Wang and Exhibits thereto, as well as other written or oral argument that Natera may present to the Court.

DATED: September 9, 2024

QUINN EMANUEL URQUHART &
SULLIVAN, LLP

By /s/ Andrew J. Bramhall

Andrew J. Bramhall
Attorneys for NATERA, INC., a Delaware
corporation, Defendant and Counterclaim Plaintiff

1 On September 5, 2024, NRG Oncology (“NRG”) informed Natera that it would not sit for a
2 deposition based upon an objection raised by Guardant. NRG, the sponsor of the COBRA study, is
3 a central witness in COBRA discovery and produced relevant documents up to August 15, 2024.
4 Given the upcoming trial, Natera seeks an order on an emergency basis authorizing the deposition
5 and instructing Guardant to withdraw the improper objection upon which NRG has relied.

6 INTRODUCTION

7 After this Court authorized COBRA discovery, Natera issued a timely subpoena for the
8 deposition of NRG for June 4, 2024. A deposition of NRG was always within the scope of COBRA
9 discovery contemplated by the parties and this Court. The parties postponed the deposition to allow
10 NRG to complete its document production, which it did on August 15, 2024. The NRG documents
11 have revealed critical information to this case, including that [REDACTED]

12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]. All these documents go to the heart of the false
17 advertising claims in this case, including for example Guardant’s claim that its tumor naive-assay
18 has 100% specificity/PPV and includes a “CHIP filter” that could screen out biological noise and
19 thus avoid false positives.

20 NRG was initially willing to sit for the requested deposition. However, Guardant interceded
21 and told NRG the deposition was untimely and only Guardant could take a deposition. On
22 September 5, 2024, NRG informed Natera that it would defer to Guardant’s objection and
23 accordingly refused to put up a witness. Natera requests that this Court order Guardant to remove
24 this obstacle and authorize the deposition to occur within 14 days. Time is of the essence given the
25 impending trial date.

26 Guardant’s objection is improper. This Court authorized COBRA discovery. There was no
27 contemporaneous objection from NRG or Guardant when Natera timely served its subpoena. Natera
28 was diligent in seeking the NRG deposition and could not proceed without completion of the

1 document production.

2 It is prejudicial to Natera to deny it an NRG deposition. Guardant has had unique inside
3 knowledge of COBRA for many months and communicated extensively with NRG. The playing
4 field with respect to COBRA was never level, and Natera learned in real-time as the NRG documents
5 were being produced just how material this information is to this lawsuit. Natera is entitled to obtain
6 admissible evidence regarding COBRA to defend itself at trial. In addition, as part of its sanctions
7 motion, Guardant's counsel accused Natera and its expert Dr. Hochster of sabotaging the COBRA
8 study, even suggesting the study may have never been terminated had it not been for Dr. Hochster's
9 actions. Natera is entitled defend itself against those allegations.

10 Natera is mindful of this Court's admonition at the August 28, 2024 hearing regarding
11 additional motions. Respectfully, however, the NRG deposition relates to already-authorized
12 discovery made in a timely manner similar to the ongoing Danish proceedings. Natera could not
13 have moved sooner because it was not until September 5, 2024 that NRG told Natera that, based on
14 Guardant's objection, it was changing its position, and there would be no deposition.

15 **BACKGROUND**

16 On March 6, 2024, this Court denied Guardant's motion to strike Dr. Hochster's
17 supplemental report on COBRA; authorized COBRA discovery; and ordered the parties to meet and
18 confer on its scope. Dkt. 493 at 13 (authorizing the parties to "conduct focused discovery as
19 previous discussed" related to COBRA). The discovery period was scheduled to end June 7, 2024.

20 In discussions leading up to the COBRA order, the parties recognized that discovery from
21 NRG was appropriate and necessary. Ex. 4 (Feb. 15, 2024, Hr'g Tr.) at 13:2-18 ("[Mr. Perloff:
22 referencing the "need to take the deposition . . . of the sponsor NRG"); Dkt. 630-4 (Feb. 21, 2024,
23 Hr'g Tr.) at 6:2-8 ("[Mr. Scolnick:] we're also seeking information from NRG. . . and also we're
24 going to depose a number of people or seek to depose a number of people at NRG.").

25 On May 16, 2024, Natera propounded a document subpoena and deposition subpoena on
26 NRG, noticing the deposition for June 4, 2024. Ex. 1. Neither NRG nor Guardant objected to the
27 deposition subpoena at the time. Guardant served its own subpoena for documents on NRG. Ex. 2.
28 NRG confirmed that it had completed its document production on August 16, 2024. Ex. 3 at 6-7.

1 On August 7, 2024, as NRG’s document production was nearing completion, Natera
 2 inquired about a deposition date. *Id.* at 15-16 (August 7, 2024 R. Landes Email). In response, NRG
 3 stated that it was amenable to sit for a deposition and appreciated Natera’s flexibility with respect
 4 to deposition format and location. *Id.* at 15 (August 7, 2024 M. Mallon Email).

5 On August 20, 2024, in response to Natera’s repeated requests for a deposition date, NRG
 6 stated that it was “in the process of hiring new counsel to take over” the deposition and that the new
 7 counsel would reach out “as soon as such counsel is hired.” *Id.* at 4 (August 20, 2024 M. Mallon
 8 Email).

9 On September 5, 2024, Guardant sent an email confirming a conversation with NRG
 10 counsel, reiterating Guardant’s objection that the deposition was not timely, and that no party may
 11 seek a deposition of NRG except for Guardant. *Id.* at 1-2 (September 5, 2024 T. Hebert Email).

12 Later that same day, NRG informed Natera it would follow Guardant’s objection and that it
 13 will not sit for a deposition absent a Court order. *Id.* at 1 (September 5, 2024 M. Mallon Email).

14 ARGUMENT

15 **I. GUARDANT’S OBJECTIONS ARE IMPROPER**

16 **A. Natera Timely Sought The NRG Deposition**

17 Contrary to Guardant’s assertions, Natera’s request for deposition is timely. This Court
 18 authorized COBRA discovery and both sides sought documents from NRG. Natera issued its
 19 document and deposition subpoena on May 16, 2024—well before the June 7, 2024 cut off. Natera
 20 could not control the speed of document production from third party NRG—despite the focused
 21 nature of Natera’s requests. And Natera could not take a deposition until the document production
 22 was complete.

23 Indeed, the same principle holds true with respect to the recent discovery dispute in
 24 Denmark. The Court had authorized Guardant to request documents from Aarhus University before
 25 fact discovery closed in July 2022; now, more than two years later, the Danish authorities responded
 26 and are facilitating Guardant’s discovery request. Dkts. 157, 622. Guardant argued to the Court
 27 that Natera cannot raise timeliness objections because the Court authorized the discovery. Ex. 5
 28 (August 28, 2024 Hr’g Tr.) at 49:7-16. And the Court agreed. In particular, the Court found that “I

1 authorized this discovery As far as exceeding the deadline, I mean, obviously here there are
2 extenuating circumstances As long as there was reasonable diligence and not in the hands of
3 the parties here . . . and there is still time to receive this . . . it's not a reason not to obtain this
4 discovery.” *Id.* at 49:17-50:9; Dkt. 637. Likewise, Natera moved with all reasonable diligence to
5 obtain discovery from NRG.

6 Guardant’s objection frustrates this Court’s order on COBRA discovery. Having permitted
7 this discovery, it would be wasteful and contrary to this Court’s order to permit document
8 production, and then preclude a deposition. The best way to obtain admissible evidence after a
9 document production is to depose a sponsoring witness. Indeed, all parties and this Court recognized
10 that NRG would possess information relevant to this case. Now that NRG has produced documents
11 directly contradicting Guardant’s litigation positions, Guardant seeks to prevent a deposition from
12 ever happening. That is improper. By standing in the way of a deposition, Guardant is preventing
13 Natera and this Court and ultimately the jury from having the necessary facts before it.

14 **B. The Sanctions Hearing Did Not Rescind Authorization**

15 Further, nothing at the July 26, 2024 sanctions hearing rescinded this Court’s prior
16 authorization of COBRA discovery. The Court permitted Guardant to take additional discovery
17 related to its motion for sanctions, but did not preclude Natera from continuing to seek authorized
18 discovery. Dkt. 630-2 (July 26, 2024 Hr’g Tr.) at 39:18-21 (“[THE COURT]: I thought what we
19 were talking about is as a result of this non-disclosure and non-production, that discovery would be
20 extended in order to fix that problem.”). Indeed, Guardant’s current position that no deposition of
21 NRG should take place contradicts the position it took at the sanctions hearing and the Court’s
22 observation that the “direct way” to find out what happened to is “to talk with” the COBRA authors
23 and designers. *Id.* at 14:2-10 (“THE COURT: when this thing first arose . . . Mr. Perloff said, well,
24 we’re going to need to contact the COBRA authors and designers and talk with them and get to the
25 bottom . . . I mean, isn’t that the direct way to find out what happened with respect to the
26 trajectory?”). In any event, the discovery sought by Natera predates the sanctions allegations.

1 II. NRG DEPOSITION IS RELEVANT AND MATERIAL

2 A. NRG Testimony Goes to The Heart of Case

3 Natera learned in real-time as NRG produced documents up to and on August 15, 2024 that
 4 COBRA discovery truly goes to the heart of this case. The relevance—recognized by this Court in
 5 authorizing the discovery—goes beyond even the “false positives” problem with Guardant’s Reveal
 6 assay that NRG referred to in its letter to participating physicians when terminating the study. Dkt.
 7 447-2 at 15 (“We have been informed by our diagnostic partner [Guardant] that a greater than
 8 anticipated number of participants may have been ‘false positives’, i.e., designated ctDNA+
 9 incorrectly.”).

10 The performance metrics at issue in this false advertising case include PPV, specificity, and
 11 the ability of a “CHIP filter” to screen out false positives that are biological noise as opposed to
 12 tumor DNA. Indeed, Guardant’s complaint alleged that it had a had a CHIP filter that would produce
 13 100% specificity and that it was literally false advertising for Natera to say otherwise. Dkt. 1 at ¶
 14 32. COBRA documents show that Natera was correct.

15 Although Guardant [REDACTED] (Dkt.
 16 605-2 at GHI00063317, 3319), [REDACTED]. In confidential FDA
 17 communications Guardant shared with NRG (and which NRG, not Guardant, produced to Natera),
 18 [REDACTED]

19 [REDACTED]
 20 [REDACTED]
 21 [REDACTED] Dkt. 632-05 at NRG-001261. On June 22, 2023—as
 22 NRG was deciding to terminate the study because of false positives—[REDACTED]

23 [REDACTED]
 24 [REDACTED] Dkt. 605-12 at GHI00063336.

25 Indeed, Guardant sent a letter to NRG on July 23, 2023, [REDACTED]
 26 [REDACTED] Dkt. 581-14 at 4. The difference is significant: with 100% specificity there are
 27 no false positives; with 95% specificity, in the expected COBRA cohort, nearly half of the positive
 28 results would be false positive—meaning patients put in the treatment arm would potentially receive

unnecessary chemotherapy.

In addition, internal NRG emails amongst NRG personnel complained about the performance of Guardant's assay in a manner directly relevant to the claims in this case. For instance, an NRG oncologist complained to a colleague that their supervising body CTEP "[REDACTED]" Dkt. 582-14 at NRG-N-000162.

Another oncologist confirmed, "[REDACTED]" *Id.* Documents also show that NRG oncologists expressed concern that "[REDACTED]" Guardant misled NRG in the same way that Guardant misled the public with their advertisements about the performance metrics of their assay.

With respect to the actual data, the NRG documents state that NRG professionals considered the results using Guardant's assay to be "[REDACTED]" and "[REDACTED]" Dkt. 582-13 at NRG-N-000046. An oncologist remarked internally at NRG that Guardant's test "[REDACTED]" Dkt. 582-15 at NRG-N-000091.

The NRG documents also show that Guardant has inside knowledge of COBRA that it hid from Natera and this Court. For instance, "[REDACTED]" Dkt. 632-10 at NRG-N-001370. "[REDACTED]" Dkt. 582-08 at GHI00063469. "[REDACTED]" Dkt. 632-11.

The bottom line from the exemplar documents cited above is that far from having an assay of 100% specificity and PPV—as Guardant maintained in advertisements and in its complaint (Dkt. 1, ¶ 32)—its product *at best* had only 95% specificity. That is a significant and material difference—indeed, "[REDACTED]" Dkt. 618-09 at NRG-000705. Not only that, but Guardant released a new product "[REDACTED]"

Guardant knew all these facts well before COBRA discovery. It was only the NRG subpoena—authorized by this Court—that led to their revelation in this lawsuit. Natera is entitled to close the loop on this relevant discovery and take an NRG deposition both to confirm the admissibility of the documents and also to learn their context and other related information.

B. Guardant’s Prior Representations Demonstrate the Relevance Of NRG

Guardant cannot now say that NRG discovery is irrelevant. Indeed, it would be unfair and prejudicial of Guardant to block an NRG deposition after telling this Court how important it would be to this case. Indeed, this Court recalled Guardant’s many statements about the need for NRG discovery. Dkt. 630-2 (July 26, 2024 Hr’g Tr.) at 28:23-29:3 (“THE COURT: You have access to the study. That’s why I gave you that time. That’s why we extended this. I mean, the whole thing, I remember having this discussion, like how long would it take, and you told me you had to get through several layers, and it built in additional time so that you could do that.”).

Furthermore, Guardant has now made serious public accusations against Natera and Dr. Hochster with respect to their alleged influence on NRG. Dkt. 630-2 (July 26, 2024 Hr’g Tr.) at 12:12-19 (accusing Dr. Hochster of “going out and communicating with the primary investigators for COBRA,” “trying to influence the trajectory of COBRA, and trying to move the samples over to Signatera for Natera’s benefit.”); *id.* at 13:12-14 (“[Mr. Scolnik:] [it]’s possible that without Dr. Hochster’s influence, interference, that COBRA would have gone a different way.”); *id.* at 22:16-22 (“[Mr. Perloff:] And [NRG], as the study designer, would probably be in the best position to comment on it, because there are some serious unanswered questions that the Dr. Hochster production has left open for us.”). Guardant cannot levy such serious accusations and then stand in the way of discovering their truth. Nor should Guardant be permitted to make unsupported allegations and then prevent Natera from defending itself.

CONCLUSION

Natera respectfully requests this Court to order Guardant to lift its objection to an NRG deposition and order such deposition to take place within 14 days.

1 DATED: September 9, 2024

QUINN EMANUEL URQUHART &
SULLIVAN, LLP

4 By /s/ Andrew J. Bramhall

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Attorneys for NATERA, INC., a Delaware
corporation, Defendant and Counterclaim Plaintiff